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APPLICATION NO.	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/115,077	Edwin Southern	7649.0001-07	8187

7590 03/01/2006  
Warren M. Cheek, Jr.  
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EXAMINER

CLOW, LORI A

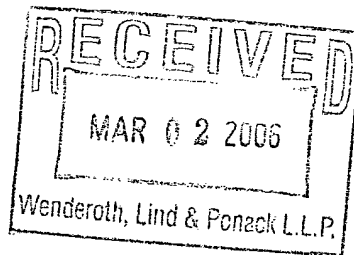
ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/01/2006

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Please find below and/or attached an Office communication concerning this application or proceeding.



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## Office Action Summary



Application No.

10/115,077

Examiner

Lori A. Clow, Ph.D.

Applicant(s)

SOUTHERN, EDWIN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

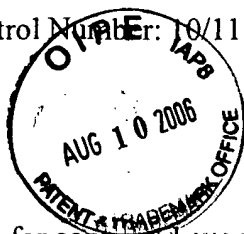
## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/16/05; 12/20/05
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_



#### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' response, filed 14 November 2005, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-16 have been cancelled. Claims 17-48 are currently pending.

#### **Information Disclosure Statement**

The Information Disclosure Statements filed 16 December 2005 and 30 December 2005 have been considered. Signed copies of PTO Form 1449 are included with this Office Action.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

This rejection is maintained from the previous Office Action of 13 July 2005 and is reiterated below.

1. As described previously, the array of claim 17 is described as having a plurality of known locations with each location containing a predetermined sequence (new limitation) located therein and each location is different from an oligonucleotide located in another location. Therefore, to further attach an array to an impermeable support is still deemed NEW MATTER, as the further attachment of an array is not supported in the specification as filed.

As the specification does not specifically define an array to be only the oligonucleotides, the interpretation of an array is one that provides a physical support for a variety of oligonucleotides positioned in certain locations. The further attachment of this array to an impermeable support, as is now claimed, is not contemplated and is therefore, NEW MATTER.

*Response to Applicant's Arguments*

See arg  
at 1,6,7

2. Applicant argues that the amendments overcome the new matter rejection, as stated above, because the claim still reads on an array attached to support, which is not supported in the original specification as filed.

3. Claims 28, 34, 39 and 43 remain rejected for containing new matter, as stated in the previous Office Action.

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The claims still recite "the array is attached to the surface of the support via at least one covalent link". There is no support in the instant specification for an array attached to a support via a covalent link, as stated above. This is NEW MATTER.

*Response to Applicant's Arguments*

4. Applicant states that "original claim 7 clearly supports the rejected claims, which original claim states that 'each oligonucleotide is bound to the support through a covalent link'". This is not persuasive because the instant claims read on an array attached to a support in which the array is attached through covalent linkage. This is not the same as the oligonucleotides being attached covalently and there is no support in the specification as originally filed for such a limitation.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 34, 36, and 39 remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by Stavrianopoulos et al. (US 4,994,373), for the reasons stated in the previous Office Action.

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*Response to Applicant's Arguments*

6. Applicant argues that "each of the independent claims now specifies that the oligonucleotides of the array have different predetermined sequences" and the "such a feature is neither disclosed nor suggested by the cited reference".

This is not persuasive. The instant specification, at page 4, provides the heading ANALYSIS OF A PREDETERMINED SEQUENCE. The paragraph that follows describes the detection of single base changes in the beta globin gene leading to sickle cell anemia. The specification goes on to state that there is a need to extend the approach to genes in which there may be a number of mutations leading to a phenotype, for example the DMD gene and the HPRT gene. The specification then describes how any known sequence can be presented completely as a set of overlapping oligonucleotides etc. (page 4, lines 4-25).

The instant specification, however, does not equate predetermined sequence, as is instantly claimed, with known sequence (from the specification). Under the heading of predetermined sequence, one might interpret "predetermined" to include a sequence that is from a certain tissue type or cell line. Therefore, it is "predetermined" what will be arrayed. However, the sequence is not necessarily "known", as in the base sequence composition.

Because the specification does not specifically define "predetermined" to be a sequence in which the base composition is known, the rejection over Stavrianopoulos et al. is maintained, as he discloses, in Example 1 in column 8, the treatment of a glass support with a silane linker for covalent linkage of single stranded DNA, reasonably an oligonucleotide, thereto to form an array for hybridization usage. In column 8, lines 40-45, the description of "various" single stranded analytes for such hybridization is reasonably interpreted as being "different"

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oligonucleotides as instantly claimed. The depressions or wells are clearly known locations also as instantly claimed. It is well known that glass (a silicon oxide as in instant claim 44) itself is impermeable as instantly required even though it also may be macroscopically porous (re-iterated from the Office Action of 25 June 2004).

### **Conclusion**

The outstanding 35 USC 112, 1<sup>st</sup> paragraph rejection over claim 48 regarding PCR products has been withdrawn on view of Applicant's amendment to the claim.

No claims are allowed.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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February 16, 2006

Lori A. Clow, Ph.D.

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*Lori A. Clow*

*Patent Examiner*



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